

# Notice of Allowability

Application No.

09/941,282

Examiner

Janet L. Andres

Applicant(s)

CHATURVEDI ET AL.

Art Unit

1646

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed 27 January 2004.
2. ☒ The allowed claim(s) is/are 1-7.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.


**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 4/15/04.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

  
JANET L. ANDRES  
PATENT EXAMINER

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael Badia on 15 April 2004.

The application has been amended as follows:

Claim 1 was amended to read:

1. A composition for treating HCV infection in a human, comprising alpha-interferon or pegylated alpha-interferon and an IMPDH inhibitor which is VX-148, wherein said IMPDH inhibitor is present in said composition in an amount such that a ratio of  $C_{avg}/C_{min}$  is between 1 to 10;

wherein:

$C_{avg}$  is average plasma concentration produced by said IMPDH inhibitor in said human; and  $C_{min}$  is estimated trough concentration produced by said IMPDH inhibitor in said human.

Claim 2 was amended to read:

2. A method for treating HCV infection in a human, comprising the step of administering to said human a composition comprising alpha-interferon or pegylated alpha-interferon and an IMPDH inhibitor which is VX-148, wherein said composition comprises said IMPDH inhibitor in an amount such that a ratio of  $C_{avg}/C_{min}$  is between

Art Unit: 1646

1 to 10:

wherein:

Cavg is average plasma concentration produced by said IMPDH inhibitor in said human;  
and Cmin is estimated trough concentration produced by said  
IMPDH inhibitor in said human.

Claim 4 was amended to read:

4. A method of producing an optimal composition for treating HCV infection in a human,  
said method comprising the steps of:

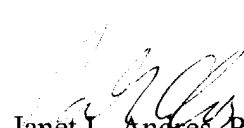
- a. administering to a human a first composition comprising a first amount of VX-148 and  
alpha-interferon or pegylated alpha-interferon;
- b . determining average plasma concentration produced by said first amount of said VX-  
148 in said human ("Cavg") ;
- c. determining trough concentration produced by said first amount of said VX-148 in said  
human ("Cmin");
- d. calculating a ratio of said Cavg to said Cmin;
- e. modifying said first amount of said VX-148  
in said first composition to a second amount of said VX-148 such that said ratio is  
between 1 to 10; and
- f. combining said second amount of said VX-148 with said alpha-interferon or said  
pegylated alpha-interferon to produce said optimal composition.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Janet L. Andres, Ph.D.  
16 April 2004